Precautionary Statement (01-50-0964)

Biomet Orthopedics, Inc.
P.O. Box 587
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Warsaw, Indiana 46581 USA

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Date: 01/06

C2a-Taper™ Acetabular System

Attention Operating Surgeon

DESCRIPTION
The C2a-Taper™ Acetabular System is a ceramic on ceramic hip articulating system. The bearing surfaces consist of ceramic femoral heads and acetabular liners. Both components are made of aluminum oxide manufactured by CeramTec AG.

The ceramic femoral heads and acetabular liners are intended to be used in conjunction with Biomet's legally marketed (U.S.) titanium acetabular shells, acetabular screws, and titanium alloy femoral stem designs with a 12/14 taper.

Acetabular Liners
The ceramic liners are available in 28mm and 32mm inside diameter (I.D.) sizes, which correspond to 37mm and 41mm outer diameter tapers, respectively. The 28mm liner is used with 48mm and 50mm shells. The 32mm liner is used with shells ranging in size from 52-70mm in 2mm increments.

Acetabular Shells
The titanium alloy shells are designed with 8 fins and the outer surface is covered with a plasma sprayed porous coating of titanium alloy (Ti-6Al-4V) powder conforming to ASTM F 1580. The shells are available in two taper diameters: 37 and 41mm. The size 37mm taper is available in two outer diameters: 48 and 50mm. The size 41mm taper is available in 52-70mm diameters in 2 mm increments.

Acetabular Screws
Titanium alloy screws in 6.5mm diameters are available for optional supplemental fixation. The 6.5mm dome screws are available in 15-70mm lengths.

Femoral Heads
The 28mm and 32mm ceramic heads are available in three neck sizes: short, medium, and long. The short neck is equivalent to a -3.5mm or - 4mm (depending on head diameter 28 and 32, respectively). The medium neck length is equivalent to standard heads (0mm), and the long neck is equivalent to a +3.5mm or a +4mm head (depending on head diameter 28 and 32, respectively).

Femoral Stems
The titanium alloy 12/14 Taperloc® femoral stems in either a standard or lateralized design are partially porous coated

with titanium alloy (Ti-6Al-4V) powder conforming to ASTM F 1580. The stems range in diameters from 5-25 mm and in lengths from 130-170 mm.

MATERIALS

Femoral heads and acetabular liners - aluminum oxide (Al2O3) conforming to ISO 6474
Acetabular shells and femoral stems - titanium alloy (Ti-6Al-4V) conforming to ASTM F 136
Acetabular screws - titanium alloy (Ti-6Al-4V) conforming to ASTM F 136

INDICATIONS

The C2a-Taper™ Acetabular System is indicated for use in primary total hip arthroplasty in skeletally mature patients with non-inflammatory degenerative joint disease (NIDJD) such as osteoarthritis, avascular necrosis, congenital hip dysplasia, and post-traumatic arthritis.

CONTRAINDICATIONS

1. Local and distant foci of infection
2. Skeletally immature patients
3. Osteoporosis
4. Metabolic disorder, which may impair bone formation
5. Osteomalacia
6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
7. Vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS

1. Seat the acetabular shell at the proper inclination and anteversion angles to decrease the chance of dislocation.
2. Always ensure proper alignment and seating of the acetabular liner before impacting to prevent chipping or damage.
3. Do not reassemble or disassemble the liner component to the acetabular shell because the locking joint and taper joint might become damaged.
4. Do not use other manufacturer's components with any of the C2a-Taper™ Acetabular System components to prevent mismatch of the tapers. Use only compatible Biomet® ceramic femoral heads (aluminum oxide) with a 12/14 taper and Biomet® titanium femoral components with a 12/14 taper.
5. Do not use any component that has been chipped, scratched, or otherwise damaged during the implant procedure. Do not use ceramic components that have been dropped, rubbed, scratched, or disfigured. Blemishes of any nature can be expected to cause failure.
6. Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.
7. Inadequate pre-closure cleaning (removal of surgical debris) can lead to excessive wear. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissues have lower adhesion strength to cement than implants handled with clean gloves.
8. Improper preoperative or intra-operative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture, and/or excessive wear. Use clean gloves when handling implants.
9. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.
10. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
11. Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on

the interior side of the pelvis.

12. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
13. All modular ceramic components must be firmly seated to prevent disassociation. Thoroughly clean and dry all tapers prior to attachment of modular heads to avoid improper seating. Do not use any component that is nicked, scratched, or otherwise altered.
14. Do not use a metallic hammer when seating the ceramic head. Use a nylon or polyethylene-seating instrument. Do not use excessive force. The ceramic head can fracture with excessive force.
15. Mal-alignment of the liner and shell components can lead to wear, device fracture, or failure. Once ceramic components have been seated do not remove and reuse.
16. Special care should be taken in the seating of the ceramic liner in the shell. Mal-alignment can cause the liner to become wedged in the shell. Subsequent attempts to remove the liner can cause chipping of the ceramic liner and/or gouging of the metal shell.
17. DO NOT USE LINERS THAT ARE CHIPPED OR SCRATCHED, OR SUSPECTED TO BE CHIPPED OR SCRATCHED.
18. Do not implant in patients with conditions or disorders that render them incapable of following directions.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight can lead to premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PRECAUTIONS

1. Surgeons must review training materials prior to implanting the C2a-Taper™ Acetabular System.
2. Do not reuse implants. While an implant may appear undamaged, microscopic imperfections may exist which could reduce the service life of the implant.
3. Components should never be re-sterilized or reused after contact with body tissues or fluids, but should be discarded.
4. Clean surgical debris from the interior of the shell prior to seating the liner into the shell to prevent accelerated bearing wear. Accelerated bearing wear may lead to early failure of the device.
5. Ensure that the outer diameter of the femoral head matches the inner diameter of the acetabular liner.
6. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as, the condition of the adjoining bone.
7. Material sensitivity reactions can result with the implantation of foreign material.
8. Intra-operative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
9. Loosening or migration of the implants can occur due to loss of fixation, trauma, mal- alignment, bone resorption, and excessive activity.
10. Periarticular calcification or ossification, with or without impediment of joint mobility can occur.
11. Inadequate range of motion due to improper selection or positioning of components can occur.
12. Undesirable shortening of limb can result from total hip replacement.
13. Dislocation and subluxation due to inadequate fixation and improper positioning can occur. Muscle and fibrous tissue laxity can also contribute to these conditions.
14. Fatigue fracture of components can occur as a result of loss of fixation, strenuous activity, mal-alignment, trauma,

non-union, or excessive weight.

15. Fretting and crevice corrosion can occur at interfaces between components.
16. Wear and/or deformation of articulating surfaces can occur.
17. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment can occur.
18. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization, or muscle deficiencies can occur.
19. Intra-operative or postoperative bone fracture and/or postoperative pain can occur.
20. Ceramic head fractures have been reported in other systems.
21. Acetabular components composed of ceramic material have limited clinical history. Because of the limited clinical experience, the long-term biological effects of ceramic wear particles are unknown.
22. Safety and effectiveness have not been established in patients with the following conditions:
    - Revision hip surgery
    - Inflammatory hip joint disease
    - Neuropathic hip joint disease
    - Obesity and high activity occupations
23. DO NOT RESTERILIZE C2a-Taper™ Acetabular System implants. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

INSTRUMENTATION/TRIAL PRECAUTION

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, and excessive wear and device failure. Intra-operative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

CLINICAL STUDY RESULTS

The following clinical data supporting the approval decision for the C2a-Taper™ Acetabular System is the same clinical data contained in P010001 for the Ceramic TRANSCEND®Articulation System owned by CeramTec AG and approved by CDRH on February 3, 2003. The following ceramic heads and liners implanted in this clinical study are identical to those used in the C2a-Taper™ Acetabular System. The stems and shells implanted in this study are similar but not identical to the stems and shells approved for use with the C2a-Taper™ Acetabular System.

Adverse Events

The adverse events related to total hip replacement surgery reported in the clinical study including 959 patients are listed in Table 1.

Table 1: Reported Adverse Events

Event	Clinical Study **(n=959)**		Whiteside Clinical Study **(n=211)**	
Systemic	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Deaths	9	0.9%	0	0%
Pulmonary Embolism	2	0.2%	2	0.9%
Deep Vein Thrombosis	4	0.4%	0	0%
Local	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**

Revisions/Removals[1]	11	1.1%	8	3.8%
Breakage/Fracture of Component[2]	5	0.5%	2	0.9%
Dislocation (single) of Component[3]	8	0.8%	3	1.4%
Dislocation (recurrent) of Component[4]	2	0.2%	0	0%
Femoral Fracture	18	1.9%	9	4.3%
Heterotopic Ossification	1	0.1%	1	0.5%
Infection: Deep, Early <>	2	0.2%	0	0%
Infection: Deep, Late > 1 year	1	0.1	0	0%
Infection: Superficial	7	0.7%	0	0%
Loosening of Component	3	0.3%	2	0.9%
Migration of Component	2	0.2%	0	0%
Persistent Foot Drop	2	0.2%	0	0%
Pain	10	1.0%	0	0%
Perforation of Femur During Reaming	2	0.2%	0	0%
Wear of Component	1	0.1%	0	0%
Subsidence of Component	3	0.3%	2	0.9%
Soft Tissue Trauma	0	0%	0	0%
Wound Problems	2	0.2%	0	0%
Other Local Complication[5]	10	1.0%	0	0%
Local-Hip	**Freq.**	**% of Pop.**	**Freq.**	**% of Pop.**
Trochanteric Bursitis	16	1.7%	1	0.5%
Trochanteric Non-union	0	0%	0	0%
Trochanteric Avulsion	4	0.4%	0	0%

Notes:

[1]See details in the following Table 9 for n=959

[2] Clinical Study: Chipping of ceramic acetabular liner during placement requiring intraoperative revision.
Whiteside Clinical Study: Broken metal peg of acetabular cup.

[3] 2 were revised for this reason.

[4] 1 was revised for this reason.

[5] Consisted of: 3 cases of irritation/inflammation; 2 cases where patients fell; 1 case of component mismatch; 1 case of liner malposition; 1 case where the acetabular shell seated too deeply in the reamed cavity; 1 case of hip flexor weakness; and 1 case where the anterior abductor pulled off.

Study Design

The study was a prospective, multi-center, historical control, clinical trial. The historical control group was later selected as the population from Whiteside Total Hips System clinical trial consisting of non-inflammatory degenerative joint disease cases. Study patients consisted of individuals over 21 years of age presenting for total hip arthroplasty due to osteoarthritis, congenital hip dysplasia, post-traumatic arthritis and avascular necrosis. A total of 329 procedures have

been performed with the Ceramic TRANSCEND® device in the original pivotal clinical population (Original Clinical Population). An additional 630 devices were implanted under Continued Access. The total number (Original Clinical Population and Continued Access) meeting the inclusion/exclusion criteria as required by the protocol is 959 procedures in 848 patients. Over a two-year period, 211 hip prostheses (179 patients) with metal femoral stems and plastic cups were implanted in the Whiteside Clinical Study.

Clinical Study Patient Assessment

Each patient was evaluated at the immediate and 6, 12, and 24-month post-operative intervals, unless otherwise indicated by complications. At each follow-up visit, a Harris Hip Score and SF-12 was administered as well as obtaining AP and lateral radiographs. Radiographs were reviewed by the implanting surgeon. There were no pre-specified success/failure criteria in the pivotal clinical study.

Demographics

For the study population, there were a total of 965 procedures performed in 854 patients at 12 sites by 19 surgeons. Six of these patients did not meet study inclusion criteria (one procedure enrolled as a replacement for a previously implanted THR and five procedures performed in patients with rheumatoid arthritis). These six procedures are excluded from this analysis. Therefore, the primary analysis sample included 959 procedures for first hip replacements performed in 848 patients.

The patient accounting and Baseline Demographics are summarized in Tables 2 and 3. Note that there were 9 deaths, none of which were related to the study or to the device.

Table 2: Patient Accounting

Evaluation Interval	Original Clinical Patient Population (n=329)			Continued Access Population (n=630)		
	TFU	EFU	AFU(%)	TFU	EFU	AFU(%)
Pre-Op	329	329	A100% (n=329)	630	630	100% (n=630)
6 months	329	323	93% (n=300)	602	602	71% (n=430)
12 months	329	321	91% (n=293)	443	442	53% (n=233)
24 months	329	321	94% (n=302)	151	150	0% (n=0)

TFU = Theoretical Follow-Up
EFU = Expected Follow-Up (Theoretical Follow-Up minus deaths and removals without replacement)
AFU = Actual Follow-up

Table 3: Baseline and Demographics

Values	Total Study Procedures (n=959)	Whiteside Clinical Study (n=211)
Mean Age in Years	51.4 Years (range 20-80)	62.7 years (range 22-87)
Gender	595 (62%) Males 364 (38%) Females	112 (53%) Males 99 (47%) Females
Mean Body Mass Index (kg/m^2)	28.8 (range 17.7-65.8)	27.1 (range 22.8-40.9)
Diagnosis Osteoarthritis Avascular Necrosis Traumatic Arthritis Congenital Hip Dysplasia	 692 (72.2%) 189 (19.7%) 36 (3.8%) 42 (4.4%)	 180 (85.3%) 31 (14.7%) 0 0
Mean Baseline Total HHS (range 1-100)	45.1 (range 8.3-95.9)	42.7 (range 11-79)
Mean Baseline Pain HHS (range 0-44)	12.9 (range 0-44)	13.2 (range 0-30)
Mean Baseline Harris ROM°(range 0-5)	3.8 (range -3.1-4.88)	4.1 (range not available)

Efficacy Results

Table 4: Efficacy Results--HHS

Primary Efficacy Assessment	Original PatientPopulation (n=329)[1]	Continued AccessPopulation (n=630)[2]	Whiteside ClinicalStudy (n=211)
Preoperative meanHHS (range)	44.8 (13-89)	45.2 (8-96)	42.7 (11-79)
2 year postop meanHHS (range)	94.8 (34-100)	88.1 (17-100)	92.7 (39-100)
% Excellent/Good Results (HHS 80-100 points) at 2 years postop	92.2%	76.9%	88.2%

Notes:

[1] Original clinical study population includes the first 329 procedures enrolled in the pivotal clinical study. This includes replacements and removals prior to 24 months (n=9), death prior to 24 months (n=7), and cases in which only a partial Harris Hip Score at 24 months or later was available (n=4)

[2] The Continued Access sample (N=630) includes procedures performed after the original population without Month 24+ outcomes. Therefore, outcomes reported were defined on the basis of Last Observation carried Forward (LOCF) and represent the latest clinical results available for that procedure.

Any Radiographic Lucency

Radiolucencies were recorded at each follow-up visit based on if they involved the entire Gruen zone (7 AP femoral zones, 7 lateral femoral zones, 3 AP acetabular zones, and 3 lateral acetabular zones). Table 5 summarizes these results.

Table 5: Any Radiolucency

Lucency	Original Study Population (n=329)	Whiteside Clinical Study (n=211)
Femoral	18 (5.5%)	66 (31.3%)
Acetabular	9 (2.8%)	56 (26.5%)
Overall	22 (6.8%)	77 (36.5%)

In addition, any subsidence was reported for the original study population for 0.9% of the femoral stems and 0.3% of the acetabular cups. In the Whiteside Clinical Study there were two instances of femoral stem subsidence (1.0%).

Implant Survivorship

Implant survivorship was the pre-specified primary endpoint in the pivotal clinical study of the Ceramic TRANSCEND® hip. Kaplan-Meier cumulative survivorship is shown in Tables 7 and 8 for the Ceramic TRANSCEND® and the Whiteside hips over time.

The cumulative Kaplan-Meier survivorship values for the femoral or acetabular component are shown in Tables 6 and 7 based on the longest duration of follow-up available in each study cohort.

Table 6: Ceramic TRANSCEND® Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	528	69	8	0.9909	0.0041
24 months	279	78	1	0.9876	0.0066

Table 7: Whiteside Clinical Study Implant Survivorship

Interval	Number Entering Interval	Number Withdrawn	Number Revised in Interval	Cumulative Survival	Standard Error
12 months	243	8	3	0.9870	0.0074
34 months	223	70	1	0.9817	0.0090
36 months	152	103	1	0.9719	0.0131
48 months	48	34	3	0.8779	0.0481
60 months	11	11	0	0.8779	0.0481

Revisions and Removals
Eleven devices out of the 959 primary patients enrolled in the trial have been revised or removed. Table 9 summarizes the clinical information pertaining to these cases.

Patient Success Criteria
Table 8 describes the proportion of patients meeting individual clinical success criteria at 2 years postoperatively.

Table 8: Patient Success Criteria at 2 Years

Patient Success Criteria	Original Patient Population (n=329)[1]	Whiteside Clinical Study (n=211)
Absence of Revision (5)	96.7% (n=318)	98.1% (n=207)
Total HHS > 70	96.8% (n=318)	95.3% (n=201)
No Complete Radiolucencies[2]	99.7% (n=328)	88.5% (n=184)

Notes:
[1] The Original Patient Population sample includes procedures in the Complete Endpoint (N=309) sample plus procedures with revisions, replacements, or removals prior to Month 24 (N=9); who died prior to Month 24 (N =7); or who had only a partial Harris Hip Score assessment at Month 24 or later (N=4). This sample was constructed in order to facilitate an analysis of efficacy and safety endpoints for hips that were at-risk for a complication and that 'completed the study.' For Complete Follow-up procedures (N=329), the Month 24+ endpoint was defined as the Month 24 value and if not available, value after Month 24 were used. Original pivotal clinical population includes the first 329 procedures enrolled in the clinical study. This includes replacements and removals prior to 24 months (n=9), deaths prior to 24 months (n=7) and cases in which only a partial Harris Hip score at 34 months or later was available (n=4).

[2] Absence of complete radiolucency were determined by radiographic evaluation for four views: acetabular AP view (3 regions), acetabular lateral view (3 regions) femoral stem AP view (7 regions), and femoral stem lateral view (7 regions). Complete radiolucency in a view was defined to be present if there was any radiolucency present in all zones comprising that view. Absence of complete radiolucency was defined to be present if none of these four views had complete radiolucency.

Table 9: Summary of Revisions and Removals

Procedures	Age/Gender	Diagnosis	Duration of Implantation	Reason for Revision/Removal
Revision of acetabularComponent with bone graft and cage implantation	50/F	AVN	84 days	Migration of acetabular component
Revision of femoral headWith a longer neck	29/F	Congenital Hip Dysplasia	1 day	Dislocation
Replaced acetabular component to larger size (32mm) and replaced femoral head to 35mm	43/M	Severe oseteoarthritis with mild hip dysplasia	1 day	Dislocation
Replacement of acetabular component, liner, and femoral head. Repair of abductor mechanism.	62/M	Osteoarthritis	38 days	Persistent dislocationfollowing closed reduction, trochanteric fracture withavulsion of abductors.

Revision followed by removal and girdlestone procedure	51/M	Traumatic arthritis	210 days	Deep infection and stitch abscess
Replacement of acetabular liner	36/F	Congenital hip dysplasia	3 days	Acetabular liner disassociated from shell
Replacement of acetabular liner and femoral head	41/M	Osteoarthritis	14 days	Increasing pain, suspected infection
Replacement of acetabular liner and femoral head	58/M	Avascular Necrosis	953 days	Excessive wear due to impingement on acetabular cup rim
Replacement of femoral head from 32mm to 28mm	50/M	Osteoarthritis	1 day	Liner/head size mismatch noted on postoperative film
Replacement of (uncemented) femoral stem to cemented stem	56/M	Osteoarthritis	657 days	Pain and progressive subsidence due to undersized (uncemented) femoral stem
Replacement of femoral stem and head	56/F	Osteoarthritis	786	Femoral component loosening

INDIVIDUALIZATION OF TREATMENT

Do not use in children. The C2a-Taper™ Acetabular System was designed for use in skeletally mature patients.

IMPLANT RETRIEVAL

The manufacturer of the C2a-Taper™ Acetabular System requests that all removed components be returned to the following address.

Biomet Manufacturing Corporation
ATTN: Regulatory Dept.
56 East Bell Drive
Warsaw, IN 46582

HOW SUPPLIED

The C2a-Taper™ Acetabular System heads and liners, as well as, the acetabular shells, stems, and bone screws (optional) are supplied sterile in individual packages. Always handle these products with powder-free gloves and avoid contact with hard objects that may damage the products. This is particularly important in handling porous coated prostheses. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

STERILITY

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma irradiation. DO NOT RESTERILIZE. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

CAUTION: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

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